

AMENDMENT

In the claims:

Please add new claims 5-8 as follows:

--5. (New) A recombinant expression vector comprising the isolated nucleic acid molecule of claim

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6. (New) The recombinant expression vector of claim 5, wherein said isolated nucleic acid molecule encodes the amino acid sequence of SEQ ID NO:2.

7. (New) The recombinant expression vector of claim 6, wherein said isolated nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO:1.

8. (New) A host cell comprising the recombinant expression vector of claim 5.--

RESPONSE

I. Status of the Claims

No claims have been canceled. No claims have been amended. Claims 5-8 have been added.

Claims 1-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**. In compliance with 37 C.F.R. § 1.121(c)(1)(ii), a marked up copy of the original claims is attached hereto as **Exhibit B**.

II. Support for the Amended Claims

Claims 5-7 have been added to specifically recite recombinant expression vectors comprising isolated nucleic acid molecules of the invention. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 11-17.

Claim 8 has been added to specifically recite host cells comprising the recombinant expression

vectors of claim 5. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 17-23.

It will be understood that no new matter is included within the newly added claims.

III. Rejection of Claims 1-4 Under 35 U.S.C. § 101

The Action first rejects claims 1-4 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

The Action indicates that the Examiner could not find the sequence Applicants referenced in the response to the previous Office Action issued in this case (mailed on December 13, 2001; “the previous Action”), which shares 99% percent homology over an extended region with the claimed sequence. This sequence is present in the leading scientific repository for biological sequence data (GenBank), and has been annotated by third party scientists *wholly unaffiliated with Applicants* a sequence “similar to epidermis specific serine protease” from humans (GenBank accession number XM_093852). The Action states that “Applicants are invited to provide alignments as evidence to support Applicant’s (*sic*) assertion of serine protease function” (Action at page 4). Applicants therefore provide, in **Exhibit C**, the alignment of the amino acid sequence of SEQ ID NO:2 (“Query”) with the amino acid sequence encoded by the nucleotide sequence disclosed in GenBank accession number XM_093852 (“Sbjct”). Thus, those skilled in the art would clearly believe that Applicants’ sequence is a serine protease.

The Action states that the utilities described for the present invention “would be applicable if one of skill in the art know (*sic*) which is (*sic*) the substrate and specificity of the alleged serine protease” (Action at page 4). However, this argument is completely misplaced. As discussed in the response to the previous Action, the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be credible or believable. The present invention has a number of substantial and credible utilities, as described in the response to the previous Action. One of these utilities, as the specification details on page 5, lines 19-21, is that the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips. Such “DNA chips” clearly have utility, as evidenced by hundreds of issued U.S. Patents, as exemplified by U.S. Patent Nos. 5,445,934, 5,556,752, 5,744,305, 5,837,832, 6,156,501 and 6,261,776. Furthermore, the skilled artisan

does not need to know the substrate or specificity of the presently claimed serine protease to use the present sequences in such DNA chips. The present nucleotide sequences are clearly related to human proteases, as detailed throughout the specification, and as described by other skilled artisans in the field. The specification also teaches that proteases are associated with a wide variety of cellular functions, such as “regulating development, modulating cellular processes, fertility and infectious disease” (specification at page 1, lines 26-28). Therefore, as the present sequences are specific markers of the human genome, and such specific markers are targets for the discovery of drugs that are associated with human disease, those of skill in the art would instantly recognize that the present nucleotide sequences would be an ideal, novel candidate for assessing gene expression using such DNA chips. Clearly, compositions that enhance the utility of such DNA chips, such as the presently claimed nucleotide sequences, must in themselves be useful.

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), as a further example of the utility of the presently claimed polynucleotides, the present nucleotide sequences have a specific utility in mapping the protein encoding regions of the corresponding human chromosome. Clearly, the present polynucleotides provide exquisite specificity in localizing the specific region of the human chromosome containing the gene encoding the given polynucleotides, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes these particular sequences so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequences.

Finally, the requirements set forth in the Action for compliance with 35 U.S.C. § 101 do not comply with the requirements set forth by the Patent and Trademark Office (“the PTO”) itself for compliance with 35 U.S.C. § 101. The PTO has issued numerous patents on polynucleotide sequences that have not been directly shown to be associated with the function of the protein that is set forth in the

specification, the conditions apparently set forth by the Examiner as allegedly necessary to comply with 35 U.S.C. § 101. The Examiner is invited to review issued U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claims short polynucleotide fragments), and recently issued U.S. Patent No. 6,340,583 (which includes no working examples). None of these issued U.S. Patents contain examples of the “real-world” utilities that the Examiner seems to be requiring in the present Action. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section IV below), Applicants submit that the presently claimed polynucleotides must also meet the requirements of 35 U.S.C. § 101.

For each of the foregoing reasons, as well as the reasons set forth in Applicants’ response to the previous Office Action issued in this case, Applicants submit that as the presently claimed nucleic acid molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1-4 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

IV. Rejection of Claims 1-4 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-4 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

Applicants submit that as claims 1-4 have been shown to have “a specific, substantial, and credible utility”, as detailed in section III above, the present rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, be withdrawn.

V. Rejection of Claim 2 Under 35 U.S.C. § 112, Second Paragraph

The Action next rejects claim 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action first rejects claim 2 as allegedly indefinite because “it is not clear how a sequence can

hybridize to another sequence since hybridization, as known in the art, occurs between nucleic acid molecules” (Action at page 5). Applicants respectfully point out that claim 2 reads, in relevant part, “(a)n isolated nucleic acid molecule comprising a nucleotide sequence” (emphasis added). Thus, the “nucleotide sequence” is, in fact, also a nucleic acid molecule (a part of the isolated nucleic acid molecule). Applicants therefore submit that the skilled artisan would understand how the nucleotide sequence could hybridize, within the parameters set forth in claim 2.

The Action next rejects claim 2 as allegedly indefinite based on the term “complement”, since “it is unclear which ‘complements’ are encompassed by the claims (*sic*)” (Action at page 6). Applicants respectfully point out that claim 2 states, in relevant part, “SEQ ID NO:1 or the complement thereof” (emphasis added). Applicants note the use of “the complement”, as opposed to “a complement”, and submit that the skilled artisan would understand this term to refer to the complete complement of SEQ ID NO:1.

Applicants submit that, for the reasons discussed above, claim 2 clearly meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants therefore request withdrawal of this rejection.

VI. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

The Action states that under the written description guidelines, the written description requirement may be satisfied “by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics” (Action at page 7, emphasis added). The Examiner seems to be requiring that the function of each of the members of the genus be known in order to satisfy the written description requirement. However, the Examiner’s stated position completely misreads the written

description requirement. In order to more clearly point this out, the section of the written description guidelines reproduced in the Action and quoted above is reproduced with numbers corresponding to the ways in which the written description requirement can be satisfied: (1) by actual reduction to practice, (2) reduction to drawings, or (3) by disclosure of relevant, identifying characteristics, i.e., (4) structure or other physical and/or chemical properties, (5) by functional characteristics coupled with a known or disclosed correlation between function and structure, or (6) by a combination of such identifying characteristics. Thus, the written description requirements can be satisfied by (1), (2), or (3), and part (3) can be satisfied by (4), (5), or (6). Applicants submit that claim 1 provides “structure or other physical or chemical properties”, specifically, the nucleotide sequence itself. There is no requirement within section (4) for functional characteristics, this being included in sections (5) and (6) only. Thus, since claim 1 satisfies section (3) by satisfying section (4), claim 1 must meet the written description requirement.

Furthermore, as set forth by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*, (43 USPQ2d 1398, 1406 (Fed. Cir. 1997)), claim 1 meets the written description requirement because the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, i.e., the *sequence itself*. Using the nucleic acid sequences of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides comprising at least 24 contiguous bases from SEQ ID NO:1 are within the genus of the instant claims, while those that lack this structural feature lie outside the genus. Claim 1 thus meets the written description requirement.

For each of the foregoing reasons, as well as the reasons set forth in Applicants’ response to the previous Action, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been overcome, and request that the rejection be withdrawn.

VII. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to make and/or use

the claimed invention. Applicants respectfully traverse.

The Action admits that the specification is enabled for “the polypeptide of SEQ ID NO:2 and the corresponding polynucleotide (SEQ ID NO:1)” (Action at page 8). The Action then states that “no disclosure of the function or structure of polypeptides encoded by polynucleotides comprising at least 24 contiguous nucleotides of SEQ ID NO:1 has been provided” (Action bridging pages 8 and 9, emphasis added).

Applicants point out that neither of the above comments are relevant to determining whether the claimed compositions meet the legal requirements for patentability under 35 U.S.C. § 112, first paragraph. Therefore, Applicants submit that the Examiner has failed to present reasoning sufficient to establish a *prima facie* case supporting the present § 112 rejection, and accordingly the rejection is improper because: 1) the Examiner’s comments were not relevant to the established legal standard of enablement; 2) the Examiner’s failure to attribute adequate weight and attention to the detailed level of teaching clearly provided in the specification; and 3) the reasoning for the enablement rejection provided by the Examiner failed to adequately consider the high level of technical knowledge that can be attributed to those skilled in the art in the field of the present invention.

A. Enablement is Established by Enabling Any Practical Use

In attempting to establish a *prima facie* case to support the § 112 rejection of the composition claims, the Action questions whether the claimed compositions are sufficiently enabled to allow those skilled in the art to practice aspects of the invention involving standard molecular biological techniques. The § 112 rejection, as applied against the nucleic acid compositions, is completely misplaced. It has long been established that composition claims are enabled by defining any practical use of the claimed compound. *In re Nelson*, 126 USPQ 242 (CCPA 1960); *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1995). “The enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins Univ. v. CellPro, Inc.*, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998), citing *Engel Indus., Inc. v. Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991).

The Examiner has already conceded that “the polypeptide of SEQ ID NO:2 and the corresponding

polynucleotide (SEQ ID NO:1)” are enabled (Action at page 8). Thus, the enablement issue should be resolved. Enablement only requires that the specification describe a practical use for the composition defined in the claims, and that a skilled artisan be able to make and use the claimed DNA segments without undue experimentation. Accordingly, by the Examiner’s own admission, the § 112 requirement has certainly been met.

The Action seems to contend that the specification provides insufficient guidance regarding the biological function or activity of certain of the claimed compositions. However, such an enablement standard conflicts with established patent law. In *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), “*Brana*”), the Federal Circuit admonished the P.T.O. for confusing “the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption”. *Brana* at 1442. The Federal Circuit went on to state:

At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase “utility or usefulness” in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using “utility” to refer to rejections under 35 U.S.C. § 101, and is using “usefulness” to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Branan at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The Examiner cites *Wands* for the proposition that the present invention could not be practiced without "undue experimentation". However, it is important to remember that, as discussed above, in assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin, supra*. In *Wands*, the P.T.O. took the position that the applicant failed to demonstrate that the disclosed biological processes of immunization and antibody selection could reproducibly result in a useful biological product (antibodies from hybridomas) within the scope of the claims. In its decision overturning the P.T.O.'s rejection, the Federal Circuit found that *Wands*' demonstration of success in four out of nine cell lines screened was sufficient to support a conclusion of enablement. The court emphasized that the need for some experimentation requiring, *e.g.*, production of the biological material followed by routine screening, was not a basis for a finding of non-enablement, stating:

Disclosure in application for the immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring 'undue experimentation,' even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or 'hybridomas,' since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one 'experiment' is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired antibodies is not excessive, in view of Applicants' success in each attempt to produce antibody that satisfied all claim limitations.

Wands at 1400. Thus, the need for some experimentation does not render the claimed invention

unpatentable under 35 U.S.C. § 112, first paragraph. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra; Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., supra.*

The Action cites a number of references to support the position that minor changes to amino acid sequences can produce different functional proteins. However, this argument is misplaced, because numerous uses of the claimed sequences do not require knowledge of any functional aspects of the amino acid sequences. Applicants point out that significant commercial exploitation of nucleic acid sequences requires no more information than the nucleic acid sequence itself. Applications ranging from diagnostics (utilizing, for example, short oligonucleotide probes or PCR primers), gene expression analysis or profiling (utilizing, for example, arrays of short, overlapping or non-overlapping, oligonucleotides and DNA chips, as described in Section III, above), chromosomal mapping (utilizing, for example, short oligonucleotide probes or full length DNA sequences), and even gene therapy (utilizing, for example, short oligonucleotide antisense primers) are practiced utilizing nucleic acid sequences and techniques that are well-known to those of skill in the art. The widespread commercial exploitation of nucleic acid sequence information points to the level of skill in the art, and the enablement provided by disclosures such as the present specification, which include specific nucleic acid sequences and guidance regarding the various uses of such sequences.

Even though the burden has been improperly shifted to Applicants, the following section is being provided to demonstrate that the specification is fully enabling in view of the detailed guidance and teaching provided in the specification within the context of the high level of technical knowledge present in the art regarding the use of nucleic acids such as those presently claimed..

B. The Specification Provides Adequate Guidance and Teaching

The Action questions the teaching and guidance in the specification for certain aspects of the present invention. However, as discussed above, this requirement is completely misplaced. There is sufficient knowledge and technical skill in the art for a skilled artisan to be able to make and use the claimed DNA species in a number of different aspects of the invention entirely without further details in a patent

specification. For example, it is not unreasonable to expect a Ph.D. level molecular biologist to be able to use the disclosed sequence to design oligonucleotide probes and primers and use them in, for example, PCR based screening and detection methods to obtain the described sequences and/or determine tissue expression patterns. Nevertheless, the present specification provides highly detailed descriptions of techniques that can be used to accomplish many different aspects of the claimed invention, including recombinant expression, site-specific mutagenesis, *in situ* hybridization, and large scale nucleic acid screening techniques, and properly incorporates by reference a montage of standard texts into the specification, such as Sambrook *et al.* (*Molecular Cloning, A Laboratory Manual*) and Ausubel *et al.* (*Current Protocols in Molecular Biology*) to provide even further guidance to the skilled artisan. Incorporation of material into the specification by reference is proper. *Ex parte Schwarze*, 151 USPQ 426 (PTO Bd. App. 1966). The § 112, first paragraph rejection is thus *prima facie* improper:

As a matter of patent office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi & Horton, 169 USPQ 367, 369 (CCPA 1971), emphasis as in original. In any event, an alleged lack of express teaching is insufficient to support a first paragraph rejection where one of skill in the art would know how to perform techniques required to perform at least one aspect of the invention. As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands, supra*. In fact, it is preferable that what is well known in the art be omitted from the disclosure. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). As standard molecular biological techniques are routine in the art, such protocols do not need to be described in detail in the specification.

Furthermore, a specification "need describe the invention only in such detail as to enable a person skilled in the most relevant art to make and use it." *In re Naquin*, 158 USPQ 317, 319 (CCPA 1968); emphasis added. The present claims are thus enabled as they are supported by a specification that provides sufficient description to enable the skilled person to make and use the invention as claimed.

C. Claim 1 is Enabled

As detailed in the sections above, all aspects of the enablement rejection under 35 U.S.C. § 112, first paragraph have been overcome. Applicants therefore respectfully request that the rejection be withdrawn.

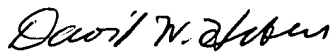
VIII. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Ramirez have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

September 5, 2002

Date



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PATENT TRADEMARK OFFICE

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Exhibit A

Clean Version of The Pending Claims in U.S. Patent Application Ser. No. 09/854,844

1. (Amended) An isolated nucleic acid molecule comprising at least 24 contiguous bases of nucleotide sequence from SEQ ID NO:1.
2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:
 - (a) encodes the amino acid sequence shown in SEQ ID NO:2; and
 - (b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:1 or the complement thereof.
3. (Amended) An isolated nucleic acid molecule according to Claim 1 wherein said nucleotide sequence is a cDNA sequence.
4. An isolated nucleic acid molecule according to Claim 3 encoding the amino acid sequence described in SEQ ID NO:2.
5. (New) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 1.
6. (New) The recombinant expression vector of claim 5, wherein said isolated nucleic acid molecule encodes the amino acid sequence of SEQ ID NO:2.
7. (New) The recombinant expression vector of claim 6, wherein said isolated nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO:1.
8. (New) A host cell comprising the recombinant expression vector of claim 5.

B

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Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application Ser. No. 09/854,844

1. (Amended) An isolated nucleic acid molecule comprising at least 24 contiguous bases of nucleotide sequence from SEQ ID NO:1.
2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:
 - (a) encodes the amino acid sequence shown in SEQ ID NO:2; and
 - (b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO:1 or the complement thereof.
3. (Amended) An isolated nucleic acid molecule according to Claim 1 wherein said nucleotide sequence is a cDNA sequence.
4. An isolated nucleic acid molecule according to Claim 3 encoding the amino acid sequence described in SEQ ID NO:2.
5. (New) A recombinant expression vector comprising the isolated nucleic acid molecule of claim 1.
6. (New) The recombinant expression vector of claim 5, wherein said isolated nucleic acid molecule encodes the amino acid sequence of SEQ ID NO:2.
7. (New) The recombinant expression vector of claim 6, wherein said isolated nucleic acid molecule comprises the nucleotide sequence of SEQ ID NO:1.
8. (New) A host cell comprising the recombinant expression vector of claim 5.

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>XM_093852 ACCESSION:XM_093852 NID: gi 18556797 ref XM_093852.1
Homo sapiens similar to epidermis specific serine
protease (LOC166414), mRNA
Length = 1095

Score = 507 bits (1291), Expect = e-141
Identities = 242/244 (99%), Positives = 242/244 (99%), Gaps = 1/244 (0%)
Frame = +1

Query: 1 MGPAGCAFTLLLLLGISVCGQPVYSSRVVGGQDAAAGRWPWQVSLHFDHNFYGGSLVSE 60
MGPAGCAFTLLLLLGISVCGQPVYSSRVVGGQDAAAGRWPWQVSLHFDHNF GGSLVSE
Sbjct: 1 MGPAGCAFTLLLLLGISVCGQPVYSSRVVGGQDAAAGRWPWQVSLHFDHNFICGGSVSE 180

Query: 61 RLILTAAHCIQPTWTTFSYTVWLGSITVGDSRKRKYVSKIVIHPKYQD TTAD-ALLKL 119
RLILTAAHCIQPTWTTFSYTVWLGSITVGDSRKRKYVSKIVIHPKYQD TTAD ALLKL
Sbjct: 181 RLILTAAHCIQPTWTTFSYTVWLGSITVGDSRKRKYVSKIVIHPKYQD TTADVALLKL 360

Query: 120 SSQVTFTSAILPICLPSVTKQLAIPFCWVTGWGKVKESDRDYHSALQEAEPPIIDRQA 179
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Sbjct: 361 SSQVTFTSAILPICLPSVTKQLAIPFCWVTGWGKVKESDRDYHSALQEAEPPIIDRQA 540

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Query: 240 GLEC 243
GLEC
Sbjct: 721 GLEC 732